REMARKS

Status of the Application

This Reply is responsive to the Office Action dated October 31, 2007. At the time of the Office Action, claims 1-5 were pending in the application. Claims 1-5 were rejected. No claims have been added, amended, or canceled. Therefore, claims 1-5 are pending and before the Examiner for consideration.

Amendments to the Specification

The specification has been amended herein to correct two typographical errors.

Claim Rejections Under 35 U.S.C. §103

Claims 1 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Englund et al., (Diagn. Microbiol. Infect. Dis. Vol. 33 p. 163-171, 1999), in view of Vary et al. (Journal of Clinical Microbiology, May 1990, p.933-937), Green et al. (Nucleic Acids Research Vol. 17 p. 9063-9073, 1989), and Mahbubani et al. (in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31). According to the Office Action:

> It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of Map because Englund et al. teach that PCR amplification of the IS900 region of Map is used to detect Map infection and Englund et al teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Englund teaches that amplification based on IS900 has been developed and widely used for the identification of Map (P. 164 first full paragraph). Vary et al. also teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al. and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design any set of primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.

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> Englund et al does not teach a method for detecting MAP infection using primers SEQ ID NO:1 and SEQ ID NO:2.

Claims 1 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Erume et al., (African Health Science vol. 1 pg. 83-89, 2001) in view of Vary et al., Green et al., and Mahbubani et al. According to the Office Action:

> It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Erume et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Erume teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represent a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.
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> Erume et al does not teach a method for detecting MAP infection using primers SEQ ID NO:1 and SEQ ID NO:2

Claims 1, 3, 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Herrewegh et al. (EP 1223225A1 published July 17, 2002) in view of Vary et al., Green et al., and Mahbubani et al. According to the Office Action:

> It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Herrewegh et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Herrewegh teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that

> PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al. and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.
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> Herrewegh does not teach a method for detecting MAP infection using primers SEQ ID NO:1 and SEQ ID NO:2.

Claims 1, 2, 3 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Corti et al. (BMC Microbiology 2002, 2:15) in view of Vary et al., Green et al., and Mahbubani et al. According to the Office Action:

> It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Corti et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Corti teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 region as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.
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> Corti et al does not teach a method for detecting MAP infection using primers SEQ ID NO:1 and SEQ ID NO:2.

Claims 1 and 3 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al, in view of Green et al. and Mahbubani et al. According to the Office Action:

> It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of Map because Vary et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection; and teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection and teaches PCR primers to the IS900 region that detect Map infection. In addition, Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.
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> Vary et al does not teach a method for detecting MAP infection using primers SEQ ID NO:1 and SEQ ID NO:2.

Applicants respectfully traverse all of the 35 U.S.C. 103 rejections and submit that none of the five combinations of references render the invention obvious within the meaning of 35 U.S.C. §103 because the combinations of (i) Englund et al., Vary et al., Green et al., and Mahbubani et al., (ii) Erume et al., Vary et al., Green et al., and Mahbubani et al., (iii) Herrewegh et al., Vary et al., Green et al., and Mahbubani et al., (iv) Corti et al., Vary et al., Green et al., and Mahbubani et al., and (v) Vary et al., Green et al., and Mahbubani et al., fail to teach or suggest all the claim limitations; and because there is no teaching, suggestion, or motivation in any of the cited references, or any combinations thereof, that would have led one of ordinary skill to modify the prior art references to arrive at the claimed invention.

In the Office Action, the examiner states that none of Englund et al., Erume et al., Herrewegh et al., Corti et al., and Vary et al. disclose primers having the sequences of SEQ ID NOs: 1 and 2 as recited in the pending claims. Applicants submit that the remaining two cited

references, Mahbubani et al. and Green et al., also fail to disclose primers having the sequences of SEQ ID NOs: 1 and 2 as recited in the pending claims. Although the examiner alleges that "one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al. and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design any set of primers anywhere along the length of the IS900 sequence..", Green et al. does not disclose PCR primers having the sequences of SEQ ID NOs: 1 and 2. Therefore, none of the cited references, nor any combinations thereof, teach all limitations of pending claims 1 -5 (i.e., "subjecting the extracted nucleic acids to polymerase chain reaction (PCR) using primers SEQ ID NO: 1 and SEQ ID NO: 2").

The present application describes Applicants' discovery that a PCR-based assay using the primers of SEQ ID NOs: 1 and 2 results in a sensitive and reliable method of detecting Map in an animal subject (see Example 1). In the Examples section of the present application, Applicants demonstrated that a PCR assay that includes primers having the sequences of SEQ ID NOs: 1 and 2 is more sensitive than a PCR assay using only primers P90 and P91 (described in Vary et al.).

Furthermore, the IS900 region is 1.45 kilobases in length, and thus a very large number of possible primer sequences exist for amplifying this region. None of the cited references, nor combinations thereof, provide any suggestion or motivation to one of skill in the art to use the specific, particular primers of SEQ ID NOs: 1 and 2 as recited in the pending claims that anneal to short, specific sequences in the IS900 region.

Based on the foregoing, Applicants submit that the cited combinations of references do not render the present invention obvious within the meaning of 35 U.S.C. §103. Applicants submit that the cited combinations fail to teach or suggest all the claim limitations and that there is no teaching, suggestion, or motivation in any of the cited references, or the combinations thereof, that would have led one of ordinary skill to modify the prior art references to arrive at the claimed invention.

In view thereof, Applicants respectfully request reconsideration and withdrawal of all 35 U.S.C. 103 rejections.

CONCLUSION

Applicants respectfully request entry of the foregoing remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 1-5 define patentable subject matter and is in condition for allowance. Accordingly, Applicant respectfully requests allowance of these claims.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are now in condition for allowance. However, Applicants request that the Examiner call the undersigned (direct line 561-671-3623) if anything further is required by the Examiner prior to issuance of a Notice of Allowance for all claims.

Although Applicants believe that no further extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any further extensions of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,
AKERMAN SENTERFITT

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Amy A. Dobbelaere, Ph.D.
Registration No. 52,088
AKERMAN SENTERFITT
P.O. Box 3188
West Palm Beach, FL 33402-3188
Tel: 561-653-5000

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